

**GAGE**

and Environmental Health Unit

July 3, 2007

Dr. Julie Spence  
Research Ethics Board  
Office of Research Administration  
St. Michael's Hospital  
30 Bond St., Toronto, Ontario  
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Department of Medicine  
University of Toronto

Department of  
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Department of Occupational  
and Environmental Health  
St. Michael's Hospital

Dear Dr. Spence,

**RE: Amendment to REB #05-143**

PI: Dr. Frances Silverman.

Study Title: "Cardiovascular Toxicity of Concentrated Ambient Fine, Ultrafine and Coarse Particles in Controlled Human Exposures"

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Enclosed please find a request for amendment our study, annual expiry date April 27, 2008. This study will allow us to examine the effects of different size fractions of particulate pollution on cardiovascular responses in healthy individuals.

After discussion and exchange with our collaborators at Harvard and the funding agency – the US EPA, we have added some points of clarification. We stated in the cover letter to SMH that we were requesting "An increase in the exposure concentration of coarse particles (from 150 to 400  $\mu\text{g}/\text{m}^3$ ) and fine particles (from 150 to 500  $\mu\text{g}/\text{m}^3$ ). These would be maximum levels that we would not go above." The point that these were indeed maximum levels was not clear, and furthermore we did not specify the actual target levels over the 2-hour exposure. The target levels would be 50% of the maximums and both the target and maximums are levels similar to those used by other researchers in the U.S. doing similar types of controlled human exposure studies with coarse and fine particles without adverse subject reactions.

As well we would like to make an addition to the protocol to add collection of urine samples pre, post and 24 hours post exposure for measurements of oxidative stress. The attached revised protocol and consent forms have been amended to reflect these changes.

Please let me know if you need anything further. Thank you for your attention to this.

Sincerely,



F. Silverman, Ph.D.  
Associate Director  
Gage Occupational and Environmental Health Unit  
223 College St., Toronto, Ontario  
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Attachments

- 1) Revised protocol
- 2) Revised consent form